

Responding to DTSC's Data Call-In for Carbon Nanotubes –

Other Issues Raised by DTSC's Questions

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Overview

- Other reporting requirements for carbon nanotubes (CNTs)
- Sharing and protecting data
- Conflicting views on safety
- Next steps for DTSC

Other Reporting Requirements

- USA/Toxic Substances Control Act (TSCA)
 - US EPA's position is that all CNTs are "new chemicals" requiring pre-manufacture notification (PMN) (73 Fed. Reg. 64,946 (Oct. 31, 2008))
 - PMN form contains numerous, detailed questions
 - Studies are optional, unless PMN submitter already has them (or acquires them during PMN review period)
 - But US EPA has imposed TSCA § 5(e) Consent Orders on every notified CNT
 - And Consent Orders require 90-day inhalation study, materials characterization data, worker PPE, limitations on processing, use, and distribution, and recordkeeping, and may prohibit releases to water (prospective)

Other Reporting Requirements (*cont'd*)

- USA/Toxic Substances Control Act (*cont'd*)
 - R&D substances exempt from PMN requirement
 - But all manufacturers, importers, processors, and distributors must report “substantial risk” information under TSCA § 8(e)
 - Also, EPA will address gaps not filled by NMSP by proposing
 - TSCA § 8(a) information-gathering rule to obtain data on existing uses, production volumes, specific physical properties, chemical and structural characteristics, methods of manufacture and processing, exposure and release information, and available health and safety data on nanoscale materials
 - TSCA § 4 test rule to require testing of several manufactured nanomaterials (CNTs?) for health and environmental effects

Other Reporting Requirements (*cont'd*)

- **USA/Toxic Substances Control Act (*cont'd*)**
 - And TSCA § 14 allows US EPA to disclose data from any “health and safety study”
 - “Any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to [TSCA].”

Other Reporting Requirements (*cont'd*)

- Canada/Canadian Environmental Protection Act 1999 (CEPA)
 - Environment Canada (EC) has said that a DSL-listed substance is “new” and requires new substance notification (NSN), if it has unique structures or molecular arrangements (e.g., fullerenes) (New Substances Program Advisory Note 2007-06)
 - NSNs have quantity thresholds, and data requirements are tiered to import/manufacture quantities
 - R&D substances not exempt from NSN
 - EC may amend NSN Regulations to address nanomaterials
 - And EC may use significant new activity (SNAc) authority to gather information on DSL-listed nanomaterials

Other Reporting Requirements (*cont'd*)

- Canada/Canadian Environmental Protection Act 1999 (CEPA) (*cont'd*)
 - Also, importers, manufacturers, transporters, processors, and distributors of a substance must report “information that reasonably supports the conclusion that the substance is toxic or is capable of becoming toxic” under CEPA § 70
 - And EC will demand information from manufacturers and importers of CNTs under a forthcoming CEPA § 71 notice
 - But CEPA §§ 313-321 allow substantiated confidentiality claims, and disclosure “in public interest” is allowed but only on a case-by-case basis, and with notice to submitter

Other Reporting Requirements (*cont'd*)

- EU/REACH Regulation
 - Nanomaterials are covered by “substance” definition in REACH
 - Manufacturers and importers must submit registration dossiers for substances manufactured or imported at or above one ton/year
 - At or above ten tons/year, registrant also must produce a chemical safety report
 - Where substances on market as bulk substance are produced or imported at nanoscale without modifications, manufacturers and importers will cover nanoscale form in registration for bulk substance

Other Reporting Requirements *(cont'd)*

- **EU/REACH Regulation** *(cont'd)*
 - Additional information about nanoscale form would be required where properties or uses differ between nanoscale and bulk forms
 - To address specific properties, hazards, and risks of nanomaterials, additional testing or information may be required
 - To determine specific hazards of nanomaterials, current test guidelines may need to be modified
 - Until specific test guidelines for nanomaterials exist, testing will be carried out under existing guidelines

Other Reporting Requirements *(cont'd)*

- **EU/REACH Regulation** *(cont'd)*
 - Substances manufactured or imported under one ton/year are exempt (covers many R&D substances)
 - And PPORD substances get five-year registration exemption upon filing a notification (Art. 9)
 - Also, following registration, registrant must update his registration with any new information (Art. 22(1)(e))
 - Some commercial information is confidential (Arts. 118(2), 119(2)), but European Chemicals Agency (EChA) will publish health and safety data on the Internet (Art. 119(1))

Other Reporting Requirements (*cont'd*)

- In responding to DTSC, ask whether you have information reportable to EPA, EC, or EChA
 - TSCA § 8(e) and CEPA § 70 cover (commercial) R&D substances and have no *de minimis* quantities
 - CEPA § 70 also covers TSCA “articles”
 - Art. 22(1) of REACH only requires updates to “registrations”
 - If there is no registration, there is no reporting obligation
 - Substances below one ton/year are not registered
 - PPORD substances are exempt for five years upon notice

Other Reporting Requirements (*cont'd*)

- There will be lots of new information on CNTs, but there also will be data gaps
 - PMNs/Consent Orders exclude R&D substances
 - NSNs have varying quantity thresholds, and NSN data are tiered to import/manufacture quantities
 - REACH registrations have a quantity threshold, and REACH delays registration of PPORD substances
 - TSCA § 8(a) and CEPA § 71 information collections will allow confidentiality claims
 - TSCA § 14 allows disclosure of “health and safety studies,” but CEPA §§ 313-321 requires notice and “public interest” finding
 - Art. 119(1) of REACH will publish health and safety data, but registration deadlines extend out to 2018

Protecting and Sharing Data

- Data available to DTSC from other reporting requirements will be “public” data
- How does industry provide DTSC responsive data without disclosing trade secrets?
 - Health & Safety Code § 57020 protects “trade secrets”
 - "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that (1) derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use, and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy
 - Can include customer or supplier lists, business plans, spreadsheets, corporate minutes and agendas, and bid specifications

Protecting and Sharing Data *(cont'd)*

- How does industry provide DTSC responsive data without disclosing trade secrets? *(cont'd)*
 - Also, DTSC may accept robust summaries of health and safety studies
 - Actual or virtual “reading room” could
 - Provide read-only access to information without creating “records” subject to public disclosure under “FOIA” laws
 - Facilitate industry’s sharing of data with DTSC and other regulators
 - Be operated for industry by third party under contract with appropriate safeguards to ensure confidentiality
- Should companies share data with one another?

Conflicting Views on Safety

- What is a “safe” CNT?
- What data support a conclusion that a given CNT is or is not a “hazardous waste?”
- Lack of monitoring and environmental fate data
 - Helps to fuel irrational public hysteria
 - Is there an opportunity for industry to jointly develop data that support the use of CNTs?
 - Pure materials
 - As used in specific products or applications

Next Steps for DTSC

- DTSC's main goal is to obtain a baseline of information for itself, other California agencies, and the public
 - For example, Department of Industrial Relations may want to develop new guidelines or regulations to protect workers
- But responses will go into the Online Toxic Information Clearinghouse (SB 509), part of the Green Chemistry Initiative (GCI)
- CNTs could be identified as a “chemical of concern” under the GCI
- And DTSC has authority to regulate chemicals under other state laws